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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,642	02/01/2002	Richard Fayrer-Hosken	235.00310101	1056

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/019,642	FAYRER-HOSKEN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,7-11 and 17-39* is/are pending in the application.

4a) Of the above claim(s) *17-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,7-11 and 29-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *March 22, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and response received March 22, 2005 is acknowledged.

Claims 1, 6, and 12-16 have been cancelled.

Claims 2-5, 7-11, 17, and 25-28 have been amended.

Claims 29-39 have been added.

Claims 2-5, 7-11, and 17-39 are pending.

Claims 17-28 stand withdrawn for the reasons set forth in the office action mailed September 22, 2004.

Claims 2-5, 7-11, and 29-39 are under examination as they relate to a fertility impairing vaccine containing avian zona pellucida protein are under consideration in the instant office action.

Applicant is thanked for updating the benefit claim in the first line of the specification.

Applicant's continued traversal of the restriction requirement is acknowledged. The restriction requirement was made final in the office action mailed September 22, 2004, and the restriction requirement is still deemed proper for the reasons of record.

Applicant's IDS, filed March 22, 2005 is acknowledged and considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of pending claims 2-5 and 7-11 under 35 USC 112, first paragraph as failing to be enabled for the use of an avian zona pellucida fertility impairing vaccine in non-avian animals has been withdrawn upon further consideration in light of the arguments made by applicant on pages 9 and 10 of the response filed March 22, 2005.

4. Claims 2-5, 7-11 stand rejected and new claims 29-39 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed for the reasons of record set forth in the office action mailed September 22, 2005.

Applicant's arguments filed March 22, 2005, on pages 10-13 of the response have been fully considered but they are not persuasive. Applicant argues that because the specification defines an immunogenic fragment of a zona pellucida protein as a fragment that elicits an immune response when administered to an animal the burden of adequate written description has been met. As was indicated to Applicant in the prior

office action, the specification does not teach which regions of avian zona pellucida proteins contain immunogenic fragments, or if the sequences and structures of the immunogenic fragments are conserved among zona pellucida proteins isolated from any avian. While it may be possible to screen for such immunogenic peptide fragments, applicant has not indicated the starting material to be used to begin such a screening assay, and has not indicated the sequence or structure that would be obtained upon completion of said assay. As such, there is no description of any part of an avian zona pellucida protein that is immunogenic, other than that whole avian zona pellucida protein is immunogenic. Therefore, the specification lacks written description of immunogenic fragments of avian zona pellucida and the rejection is maintained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. The rejection of pending claims 2-5, 10, and 11 under 35 U.S.C. 102(a) as being anticipated by Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) has been removed due to applicant's amendment of the base claim from which these claims depend. The new

base claim includes limitations on the adjuvant to be used as part of the vaccine, and these newly included adjuvant limitations are not taught by Waclawek et al. As such the rejection of record has been obviated.

7. Applicant's amendment to the claims received on March 22, 2005 in response to the office action mailed September 22, 2004 has necessitated the following new grounds of rejection.

8. Claims 34-38 are rejected under 35 U.S.C. 102(a) as being anticipated by Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document).

Waclawek et al. teach a composition that contains chicken zona pellucida glycoprotein ZPC (chZPC), and its use in generating an antibody response in rabbits (see entire document, particularly page 1231, left column, second paragraph of the section titled Protein Sequencing and Immunological Procedures). The chZPC characterized by Waclawek et al. is disclosed as having an approximate molecular weight of 34 kD, but the apparent molecular weight is variable, possibly due to differences in the carbohydrate moieties attached to chZPC (see particularly the first two paragraphs of the results section on the right column of page 1232, the first two paragraphs of the right column of page 1235, and Figures 1, 5, 8, and 9). Comparison of the Figures 1, 5, 8, and 9 appears to indicate that the apparent molecular weight can vary between 34 kD and 43 kD, since changes in weight are seen depending upon if the

material is isolated from laid eggs or follicles, and if the material is treated with a reducing agent, such as DTT, prior to resolution by gel electrophoresis (particularly compare the -/+ DTT immunoblot lanes of Figure 1, and Figure 5, which indicates an apparent weight of 43 kD). As such, the chZPC used by Waclawek et al. to vaccinate rabbits and generate an antibody response contains avian zona pellucida protein of the apparent molecular weights 35 and 40 kD. Also, since the claims are drawn to immunogenic fragments, the chZPC isolated by Waclawek et al. is immunogenic and as such is considered to be a fragment of the 70 kD zona pellucida protein (and is also a fragment of the 40 kD and 35 kD zona pellucida proteins as well).

Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2-5, 10, 11, 29, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) in view of Cox et al. (Vaccine, (1997) 15:248-256, see entire document).

The teachings of Waclawek et al. have been discussed above and in the office action mailed September 22, 2004. These teachings differ from the claimed invention in that Waclawek et al. do not used the adjuvants currently recited in claim 29 as part of their chZPC vaccine composition that induces an antibody response when administered to rabbits.

Cox et al. teach that aluminum salts, notably aluminum hydroxide, have been widely used in human and veterinary vaccines since 1930 and induce the development of strong antibody responses (see particularly the middle of the right column of page 248). Vaccines that utilize aluminum salts offer the advantages of being inexpensive, safe, and simple to formulate (see particularly the last sentence of the Aluminum salt section on page 250). The immunogen is bound by electrostatic interactions to the aluminum salt adjuvant and forms a short term depot that traps antigen at the immunization site and slowly releases the antigen over a period of about a week, thus

forming a time-release delivery vehicle (see particularly the sections titled Depot generation and Aluminum salts in the right column of page 350, Table 1 on page 249 and table 2 on page 251).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to substitute aluminum hydroxide for the adjuvant used by Waclawek et al. in their chZPC compositions to gain the advantages of inducing a strong antibody response, low cost, safety, and ease of formulation as taught by Cox et al.

12. Claims 2-5, 7, 8, 10, 11, 29, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) in view of Willis et al. (J. Equine Vet. Sci, (1994) 14:364-370, reference C92 on Applicant's IDS dated 2/14/03, see entire document).

The teachings of Waclawek et al. have been discussed above and in the office action mailed September 22, 2004. These teachings differ from the claimed invention in that Waclawek et al. do not used the adjuvants synthetic trehalose dicorynomycolate or squalene oil in their vaccine composition comprising chZPC that induces an antibody response.

Willis et al. teach the use of synthetic trehalose dicorynomycolate and squalene oil as adjuvants for delivery of a vaccination via a biobullet (see entire document, particularly the summary and second full paragraph of the left column of page 366).

The use of synthetic trehalose dicorynomycolate and squalene oil as adjuvants has an advantage over the use of Freund's adjuvant (the adjuvant used by Waclawek et al.) in that their use does not result in unwanted side effects of vaccination, such as abscess formation at the injection site which is a common side effect of vaccination with Freund's adjuvant (see particularly the second complete paragraph in the left column of page 369). Further, the use of biobullet vaccination techniques as taught by Willis et al. offer the advantages of a delivery vehicle that allows for remote administration that maximizes treatment efficiency while minimizing danger and harassment of the animal (see particularly the first paragraph of the Discussion section on page 368).

Therefore, a person of ordinary skill in the art would have been motivated at the time the invention was made to substitute synthetic trehalose dicorynomycolate and squalene oil for Freund's adjuvant in the vaccine compositions of Waclawek et al. for the advantage of minimizing unwanted side effects such as vaccination site abscess formation as taught by Willis et al. A person of ordinary skill in the art would also have been motivated at the time the invention was made to deliver the chZPC vaccine of Waclawek et al. via a biobullet to gain the advantages of maximized treatment efficiency with minimized danger and harassment of the animal as taught by Willis et al.

13. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) in view of Dean (US Patent

5,641,487, of record as reference A22 on Applicant's IDS dated 2/14/03, see entire document).

The teachings of Waclawek et al. have been discussed above and in the office action mailed September 22, 2004. These teachings differ from the claimed invention in that Waclawek et al. do not use chZPC that has been conjugated to an immunogenic carrier protein.

Dean teaches that it is well known to couple antigens to carrier proteins to gain the advantage of enhancing the immune response to the target antigen (see entire document, particularly column 8, lines 10-64, Example 3, and Example 4).

Therefore, a person of ordinary skill in the art would have been motivated at the time the invention was made to couple the chZPC of Waclawek et al. to a carrier protein to gain the advantage of increasing the immune response to the chZPC antigen as taught by Dean.

14. Claims 9 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document) in view of Bagavant et al. (Biology of Reproduction (1997), 56:764-770, of record as reference C5 on Applicant's IDS dated 2/14/03, see entire document).

The teachings of Waclawek have been discussed above and in the office action mailed September 22, 2004. These teachings differ from the claimed invention in that

Waclawek et al. do not use chZPC in a composition that also contains an immune cell epitope from a parasite.

Bagavant et al. teach the use of immune cell epitopes from the malarial circumsporozoite protein of *Plasmodium faciparum* as part of a zona pellucida fertility impairing vaccine (see entire document, particularly the abstract). These malarial epitopes provide a known helper T cell epitope that ensures a strong antibody response (see particularly Figures 1-4, and the last sentence of the second full paragraph of the left column of page 769).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an immune cell epitope from *P. faciparum* as taught by Bagavant et al. as part of the chZPC vaccine composition taught by Waclawek et al. to ensure a strong antibody response as taught by Bagavant et al.

15. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. No claims are allowable.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 19, 2005

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